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EXAMINER

HANDY, DWAYNE K

ART UNIT

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/293,669</b>	Applicant(s) <b>Doleman et al.</b>
Examiner <b>Dwayne K. Handy</b>	Art Unit <b>1743</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Jan 6, 2003

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 9-15 and 17-20 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 9-15 and 17-20 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 19 is objected to because of the following informalities:

First, applicant appears to have made an error in presenting this claim. In step (b) applicant recites contacting the array with a “10% constant fraction”. The Examiner believes this to be redundant. A 10% fraction would be constant. Also, claim 19 appears to be a duplicate of claim 18 when one considers all of the limitations of the claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-  
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Manzoni et al. (6,066,249). Manzoni teaches a method for calibrating an instrument for the analysis of blood

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gases and is used for the determination of the pH, pO<sub>2</sub>, and pCO<sub>2</sub>. The instruments comprise a series of electrochemical sensors that possesses ion-sensitive electrodes and gas-sensitive electrodes. The method is described in general in columns 3 and 4 and includes providing a solution of known amounts of the compound of interest and recording the current signal of the electrode at the known values of pO<sub>2</sub>. Preferably, the reference solutions contain known amounts of oxygen and carbon dioxide with pO<sub>2</sub> and pCO<sub>2</sub> measured by tonometer during production of the known solutions (col. 4, lines 39-50). It was found, surprisingly, that determination of the pO<sub>2</sub> in blood samples upon the implementation of calibration method described by Manzoni gave very precise results and an accuracy which was comparable with that of similar determinations carried out by means of calibration with gas mixtures that are reliable (column 5, lines 4-23).

In the reference claims 1, 7-9, and also Example 2, recite steps which include exposing a sensor array to known amounts of oxygen and carbon dioxide. The Examiner considers the exposing of a sensor array to a first compound (oxygen) which produces a first response intensity and a second compound (carbon dioxide) which produces a second response intensity and then comparing their responses to see if the sensor provides an accurate response as meeting the limitations of claims 9-11. The purpose of using a sensor is to provide a response that mimics human detection ability. The Examiner considers calibrating a sensor as described here to be a mimicking of the human nose detection ability since the exposing of the sensor to a known amount of shows that the sensor does, indeed, operate correctly.

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***Inventorship***

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manzoni et al. (6,066,249). Manzoni, as described above in paragraph 2, teaches every element of claims 17-20 except for the specific step order cited in claim 17 and the specific fractions cited in claims 18 and 19. Manzoni does teach varying the partial pressure of one component in calibrating the sensor and shows several examples of reading oxygen levels that vary, including some readings in which the levels of oxygen decrease from the first reading to the next – as is the case in claim 17. It would have been obvious to one of ordinary skill in the art, then, to perform steps (a) and (b) of claim 17 in any order – even simultaneously – provided that the sensor still reads the first and second compound and provides a response intensity to each compound. One would make the reading simultaneously to save time. Also, the Examiner believes it would have been obvious to one of ordinary skill in the art to expose the sensor array to *any* fraction of a first and second compound as long as the response to each compound can be compared to their known amounts for the purpose of calibrating or validating the correct operation of the sensor. The exposing of detection instruments to known fractions of compounds is a well known step for calibrating instruments.

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8. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manzoni et al. (6,066,249) in view of Lewis et al. (5,571,401). Manzoni teaches every element of claims 12-15 except for the sensor types claimed in claims 12-14 as well as the compounds contained in column 15. Lewis teaches a sensor array for detecting analytes in fluids. The array is comprised of conductive elements (leads) which provide a resistance response when contacted with an analyte at a first concentration and then a different response when contacted with an analyte at a second concentration (Abstract). The array is best shown in Figures 1A-1C and described in columns 6-8. Of particular importance to the instant claims is a passage from column 7 where Lewis describes the operation of the device. Starting at line 29: "The fluids may be liquid or gaseous in nature. The first and second fluid may reflect sample from two different environments, a change in the concentration of an analyte sampled at two time points, a sample and a negative control, etc. The sensor array necessarily comprises sensors which respond differently to a change in analyte concentration.... In a preferred embodiment, the temporal response of each sensor is recorded. The temporal response of each sensor may be normalized to a maximum percent increase and percent decrease in resistance which produces a response pattern associated with the exposure of the analyte. By iterative profiling of known analytes, a structure-function database correlating analytes and response profiles is generated. Unknown analyte may then be characterized or identified using response pattern comparison and recognition algorithms."

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Based on these passages from Lewis, it would have been obvious to one of ordinary skill in the art to combine the method of calibration from Manzoni with the sensor of Lewis. Lewis teaches a sensor which, when exposed to changes in analyte compositions, provides a response specific to that particular concentration. Lewis' sensor also uses known response patterns formed from other compounds to determine the identity of unknown samples. One would use a method of calibration on the sensor of Lewis to insure that the known response patterns are accurate and to insure that the sensor operate correctly for varying concentrations of analytes. Lewis teaches the various compounds which may be detected when using their device in columns 7-8 as well.

***Response to Arguments***

9. Applicant's arguments with respect to the reference Gross et al. have been considered but are moot in view of the new ground(s) of rejection. The Examiner believes that the prior art cited in the current rejection is more appropriate.

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gumbrecht et al. (5,763,760) teaches a method of exposing a single sensor element to known amounts of fluids in a calibration gas. Nelson et al. (5,246,859) discloses a method of stabilizing a carbon dioxide sensor. Hacker et al. (6,101,406) teaches a cassette for measuring

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blood parameters that includes a calibration fluid. Deetz et al. (5,231,030) also teaches a calibration system using a fluid containing a dissolved known amount of a compound. Nestor et al. (5,234,835) shows a precalibrated sensor system for determining blood parameters.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700

dkh

March 24, 2003